

REMARKS/ARGUMENTS

Claims 1 and 4-27 are pending. By this Amendment, claims 1, 4, 8, and 13 are amended, and new claims 14-27 are added. Claims 2 and 3 are canceled.

Claims 1, 2, 7 and 13 were rejected under 35 U.S.C. §102(b) over Replogle (U.S. Patent No. 3,117,574). This rejection is respectfully traversed.

Claim 1 as amended herein includes the subject matter of claims 2 and 3 which was not rejected as being anticipated by Replogle. Accordingly, Applicants respectfully submit that the anticipation rejection under 35 U.S.C. §102(b) has been obviated.

With regard to independent claim 7, Replogle does not teach or suggest a cushion for use with a nasal mask comprising an outer membrane including a face contact portion to form a seal with the patient and an underlying rim positioned below the membrane. Replogle discloses the use of an oro-nasal breathing mask 40 which is described as being "rather stiff". See column 2, lines 53-58. The mask 40 is provided on its inner peripheral edge 42 with a soft face engaging annular cushion 43. There is no teaching or disclosure in Replogle that cushion 43 includes an outer membrane including a face-contact portion to form a seal with the patient, and an underlying rim positioned below the membrane as recited in original independent claim 7.

Moreover, Replogle does not teach or suggest that the membrane and the rim are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient, as recited in independent claim 7. There is no teaching or disclosure that Replogle is formed in position to accommodate pre-adult or small sized adult patients. In particular, Replogle's main object is to enable the individual crew member who is wearing the mask to normally go about his regular duties unimpeded by the mask. Replogle's crew member

is one who is engaged in the flying of aircraft, not a pre-adult patient or a small sized adult patient; note that the assignor is Scott Aviation Corporation of Lancaster, New York.

Further, Replogle does not teach or suggest that a frame connection portion is provided opposite the face contact portion, wherein the cushion has a generally stepped and/or sloped profile such that a projected area of the frame connection portion is generally larger than an area defined by the face contact portion of the membrane, as recited in claim 13. If anything, Replogle appears to teach the opposite structure, as best seen in Figures 2 and 3.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 3, 4, 8 and 12 were rejected under 35 U.S.C. 103(a) over Replogle in view of Wright (U.S. Patent No. 4,657,010). This rejection is respectfully traversed.

At the outset, the introductory portion of the rejection indicates that claims 3, 4, 8 and 12 are rejected, although claims 9, 10 and 11 are also mentioned in the body of the rejection. Accordingly, it is unclear whether claims 9-11 are part of the formal rejection.

The subject matter of claim 3, along with that of claim 2, has been placed into independent claim 1. As acknowledged in the Office Action, Replogle does not teach or suggest this subject matter. In addition, Wright does not make up for this deficiency. In particular, the Office Action indicates that Wright provides a mask that can be adjusted to fit the facial dimensions of the wearer. Specifically, Wright's mask is made adjustable by the use of overlapping upper and lower sections which may be connected with one another in various configurations depending on the size of the patient. The area of overlap can be made larger or smaller depending on the facial length of the wearer, e.g., the area of overlap is larger for smaller adults, and smaller for a larger adult. See the Abstract.

Accordingly, the combination of Replogle and Wright does not teach or suggest the subject matter of independent claim 1. First, claim 1 specifies ranges for first, second and third distances which are not taught in Wright. Applicants selected these distances in order to accommodate either a pre-adult patient or a small sized adult patient. Wright does not remotely teach or suggest the specific ranges recited in claim 1.

Second, while Wright teaches the use of an adjustable face mask, that is not what Applicants claim. Instead, Applicants claim straps including a yoke having first, second, third and fourth dimensions. Wright does not teach that its straps 32 have any specific dimensions. Rather, Wright teaches first and second components of a mask shell that are intended to accommodate for patient's having different facial lengths. There is not teaching or suggestion in Wright that there is any connection between the adjustability of the upper and lower sections with the dimensions of the strap 32.

Third, the Examiner states that a review of the specification found no criticality on why the yoke must be the particular dimensions as described in Applicants' specification. In response, Applicants respectfully submit that it is incumbent on the Patent Office to establish a *prima facie* case of obviousness as to why one of ordinary skill in the art would have modified the Replogle/Wright combination to arrive at the claimed subject matter. The Office Action has failed to establish such *prima facie* case of obviousness, merely stating that the dimensions recited in the claims are obvious matters of design choice. Moreover, Applicants' specification establishes that the claimed dimensions have significance. For example, as described in paragraph 77 of the original application, the design of adult masks typically take into account body mass and racial nose characteristics. For example, the East Asian-shaped nose typically has a lower nasal bridge region compared to the Caucasian-shaped nose. However, Applicants

discovered that below the ages of 5 to 7, there are few racial distinctions in children. In particular, neonates, infants and young children have no nasal bridge. Not only do children have smaller heads and faces than adults, their heads and faces are differently shaped. In accordance with an aspect of the invention, a system of mask and headgear sizes has been developed in which a minimal set of components can be used to fit the widest range of people. See original paragraph 77 of the specification.

Accordingly, Applicants respectfully submit that the dimensions recited in the claims were selected in order to meet the above criteria.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 5 was rejected under 35 U.S.C. §103(a) over Replogle in view of Norfleet (U.S. Patent No. 6,418,929). This rejection is respectfully traversed at least because the subject matter of claim 5 depends from claim 1, and is patentable by virtue of that dependency.

In addition, Applicants have rewritten original claims 1 and 5 into independent form as new claim 14. As acknowledged in the Office Action, Replogle does not teach or suggest this subject matter. In addition, Norfleet does not make up for this deficiency since Norfleet teaches an arrangement where first and second straps are not joined to one another at a rear portion of the patient's head in use via a cross-over member. In particular, Norfleet teaches an arrangement where first and second junctures 75 and 80 are positioned substantially above a corresponding ear 82 of the infant 12. See, column 4, lines 54 and 55. In addition, upper rear strap 62 and lower rear strap 64 are joined to form a loop 70 which is positional about the crown 36 of the infant 12. See column 4, lines 26-28. Straps 62 and 64 are not joined to one another at a rear portion of the patient's head via a cross-over member.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 6 was rejected under 35 U.S.C. §103(a) over Replogle in view of Anscher (U.S. Patent No. 6,000,109). This rejection is respectfully traversed at least because claim 6 depends from claim 1 which is patentable for the reasons described above.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 14-27 are added for the Examiner's consideration. Claim 14 was discussed above. In addition, the applied prior art does not teach or suggest headgear including a yoke being constructed and arranged to accommodate a pre-adult patient in the age range of 2 to 6 years, or 6 to 16 years, as recited in independent claims 15 and 16, respectively. Dependent claims 17-27 define further features.

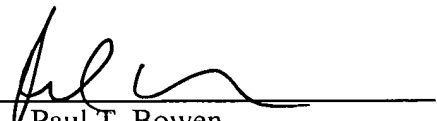
In view of the above amendments and remarks, Applicants respectfully submit that all the claims are patentable and that the entire application is in condition for allowance.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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